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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/523,102	03/10/2000	Erwin Si	03654.0255	4492

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EXAMINER	
SAUCIER, SANDRA E	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 05/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/523,102	SI ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42 and 67-70* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42 and 67-70* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *10 March 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-42, 67-70 are pending and are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-42 and 67-70 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11, 13, 30-37, 39 of copending Application No. 09/648446. Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to the same method of topically applying a therapeutic agent (batimastat) to the eye for treatment of posterior segment of the eye (retina).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 67 and 69 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear from the construction of the claim what is excluded from the composition since it both comprises a polymeric agent to which other compounds may be added and consists essentially of batimastat. The metes and bounds are not clear. A composition should "consist essentially of" not merely a component of that composition. It is the composition as a whole which excludes components added which materially change its properties.

Applicants argue that a practioner would know what is excluded by use the transitional phrase, but fail to explain what might be excluded and how the use of this phrase might overcome the art rejections. Thus, in the absence of an explanation, the rejection remains.

Claim Rejections - 35 USC § 102

Claims 7-12, 14, 23-30, 32, 38-42, 69 and 70 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,767,153.

The claims are directed to the one step method of preventing retinal neovascularization by topically administering to the eye a composition comprising 0.01-3% w/w batimastat of the claim specific formula and a polymeric suspension agent. The mammal which is the recipient of this administration is a mammal that is susceptible to developing retinal neovascularization. Other claims are broader in some aspect of the composition limitations.

US 5,767,153 teaches the topical administration to a recipient of a composition comprising batimastat (0.3 weight %) and polycarbophil (1.15 weight %). Since everyone is susceptible to developing retinal neovascularization by developing the diseases of the retina and/or traumatic ocular insults as described on page 1 of the instant specification, and no specific type of recipient is required by the claims, the recipient is interpreted to be the same as the recipient of the claims. As the composition administered is the same (batimastat and polycarbophil), the concentrations of the components of the composition is the same and the patient required is the same, the inherent result of the one method step would be the same, that is prevention of retinal neovascularization.

" To invalidate a patent by anticipation, a prior art reference normally needs to disclose each and every limitation of the claim. See Standard Havens Prods., Inc. v. Gencor Indus., Inc., 953 F.2d 1360, 1369, 21 USPQ2d 1321, 1328 (Fed. Cir. 1991). However, a prior art reference may anticipate when the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it. See id.; Verdegaal Bros., Inc. v. Union Oil Co. of Cal., 814 F.2d 628, 630, 2 USPQ2d 1051,1053 (Fed. Cir. 1987). Under the principles of inherency, if the prior art necessarily functions in accordance with, or includes, the claimed limitations, it anticipates. See In re King, 801 F.2d 1324, 1326, 231 USPQ 136, 138 (Fed. Cir. 1986). Inherency is not necessarily coterminous with the knowledge of those of ordinary skill in the art. See Titanium Metals, 778 F.2d at 780. Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art. See id. at 782. However, the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer. See id. at 782 ("Congress has not seen fit to permit the patenting of an old [composition], known to others . . . , by one who has discovered its . . . useful properties."); Verdegaal Bros., 814 F.2d at 633.

This court's decision in Titanium Metals illustrates these principles. See Titanium Metals, 778 F.2d at 775. In Titanium Metals, the patent applicants sought a patent for a titanium alloy containing various ranges of nickel, molybdenum, iron, and titanium. The claims also required that the alloy be "characterized by good corrosion resistance in hot brine environments." Titanium Metals, 778 F.2d at 776. A prior art reference disclosed a titanium alloy falling within the claimed ranges, but did not disclose any corrosion-resistant properties. This court affirmed a decision of the PTO Board of Appeals finding the claimed invention unpatentable as anticipated. This court concluded that the claimed alloy was not novel, noting that "it is immaterial, on the issue of their novelty, what inherent properties the alloys have or whether these applicants discovered certain inherent properties." Id. at 782. This same reasoning holds true when it is not a property, but an ingredient, which is inherently contained in the prior art. The public remains free to make, use, or sell prior art compositions or processes, regardless of whether or not they understand their complete makeup or the underlying scientific principles which allow them to operate. The doctrine of anticipation by inherency, among other doctrines, enforces that basic principle." See Atlas Powder Co. v. IRECO Inc. 51 USPQ2d 1943 (Fed. Cir. 1999).

Thus, a reference may be anticipatory if it discloses every limitation of the claimed invention either explicitly or inherently. A reference includes an inherent characteristic if that characteristic is the "natural result" flowing from the reference's explicitly explicated limitations. Continental Can Co. USA, Inc. v. Monsanto Co., 948 F.2d 1264, 1269, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991).

Response to Arguments

Applicants argue that the examiner has not shown that the result of the methods of '153 necessarily prevent retinal neovascularization. Since the claimed one step method of administering the same agent in the same fashion is the same method as taught in the prior art, the result would inherently be the same. If applicants' claimed method prevents neovascularization, the method practiced in '153, which is the same method would also prevent neovascularization. Applicants argue that the examiner confuses the concept of a mammal possibly developing a disease which could lead to the development of retinal neovascularization with a mammal that is susceptible of developing retinal neovascularization as the result of having such a disease or condition. Please note that the independent claim recites that the subject is a mammal susceptible to developing retinal neovascularization. Since all mammals are susceptible to developing retinal neovascularization, this mammal is considered to be the same mammal as that in the prior art method. No disease condition is mentioned in the claimed methods.

Claim Rejections - 35 USC § 103

Claims 1-42, 67-70 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,767,153 [A] in view of WO 97/41844.

The claims are directed to a one step method of treating or preventing retinal neovascularization in an animal comprising topically administering a composition comprising (0.01-3% w/w) batimastat and in some of the claims, a polymeric suspension agent, particularly polycarbophil.

The references are relied upon as explained below.

US 5,767,153 discloses a composition comprising 0.3% batimastat and 1.15% polycarbophil useful for topical ophthalmic administration, (col. 2, l.7 and example 7). It teaches that inclusion of medicaments such as batimastat in combination with polycarbophil increases its bioavailability to the target tissue in the eye (col. 2, ls. 19-21).

The reference lacks the disclosure of use of the composition of polycarbophil and batimastat for the treatment of retinal neovascularization.

WO 97/41844 discloses that batimastat is an angiostatic agent (Table 1) and as such is effective in compositions for the treatment of diseases where neovascularization arises such as diabetic retinopathies, proliferative virtreoretinopathies and other diseases (page 1, second paragraph and page 5, table 1). Compositions comprising metalloproteinase inhibitors such as batimastat, which is a preferred angiostatic agent (page 19, l. 9) are in topical ophthalmic formulations (claim 20). The compositions may be used to prevent retinal neovascularization (page 20, l. 11).

The substitution of the composition of batimastat and polycarbophil disclosed in US 5,767,153 for the batimastat composition taught in the topical ocular treatment method of WO 97/41844 would have been obvious because batimastat is known to be useful to treat retinal neovascularization as taught in '844 and the formulation of batimastat with polycarbophil as a suspension agent is taught in '153 to be particularly advantageous in terms of delivering a sustained dosage of a sparingly water soluble active ingredient such as batimastat over time.

One of ordinary skill in the art would have been motivated at the time of invention to substitute a composition of batimastat for a composition of batimastat and polycarbophil to treat retinal neovascularization in order to obtain the results as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Response to Arguments

Applicants argue that '844 nowhere mentions the treatment or prevention of retinal neovascularization by administration of a batimastat (compound) other than, at best, in a putative combination treatment. While the reference does teach the use of combinations of angiostatic compounds, of which batimastat is one, the claims do not exclude the addition of other compounds to the composition

Allowable Subject Matter

Presentation of a claim drawn to treating retinal neovascularization in a mammal comprising topically administering to the eye a composition consisting of the compound of formula 1 (batimastat) and a polymeric

uspension agent where about 0.01 to about 3% by weight is the batimastat compound, might be found to be allowable upon resolution of the provisional double patenting rejection.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is 571-272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sandra Saucier
Primary Examiner
Art Unit 1651